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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,100	08/22/2001	David B. Weiner	UPN-4099	2243

7590 07/02/2004

COZEN O'CONNER
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PHILADELPHIA, PA 19103

EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,100	WEINER ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07052002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Applicants' election of Group XX (claims 32 and 33) in the response filed 05 April, 2004, is noted. Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)). Applicants canceled claims 1-31 without prejudice or disclaimer, amended claims 32 and 33, and introduced new claim 34. Claims 32-34 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed 05 July, 2002, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 32 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Sato *et al.* (1990). Sato and colleagues disclose pharmaceutical compositions comprising HIV-1 Vpr-specific

antibodies and an acceptable pharmaceutical carrier. Accordingly, this teaching meets all of the claimed limitations.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33 and 34 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed toward a method of treating individuals exposed to or infected with HIV by administering anti-Vpr antibodies.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate

guidance pertaining to a number of these considerations as follows:

Inadequate Direction/Guidance Provided

The disclosure fails to provide adequate guidance pertaining to the structural and functional characteristics of the anti-Vpr antibodies present in the pharmaceutical composition. The specification is silent pertaining to the epitope(s) recognized, the affinity of the antibody composition, the avidity of the antibody composition, and the pharmacological properties (i.e., serum half-life, bioavailability, clearance rate, sequestration by serum proteins, target distribution, target levels, etc.). The skilled artisan would require a knowledge of these various properties before attempting to administer the antibody composition to a patient.

Claim Breadth is Excessive

The claims are broadly directed toward any population of anti-Vpr antibodies. Thus, they may include specific monoclonal reagents (none of which are described in the specification), polyclonal reagents, or recombinant antibodies. The claims do not specify any type of neutralizing activity or other properties for the antibodies. In order to practice the claimed invention the skilled artisan would need a purified, well-characterized reagent (i.e., a Mab produced from a specific hybridoma). However, the specification is silent pertaining the properties of any given antibody composition.

State-of-the-Art

The state-of-the-art vis-à-vis the treatment of HIV infection using immunotherapeutics can be characterized by unpredictability and frequent failure. This is not surprising since the correlates of protective immunity remain to be elucidated (Burton and Moore, 1998; Feinberg and Moore, 2002; Moore and Burton, 1999; Johnston, 2000; Letvin, 1998). Thus,

the skilled artisan, even if armed with a highly specific neutralizing reagent, cannot predict if that reagent will have a meaningful clinical effect. Each antibody composition must be tested empirically, preferably in a human host since most animal models are inadequate and do not allow the direct extrapolation of findings from one system to another. Moreover, some passive immunotherapy studies have reported that there was no clinical benefit in HIV-infected patients receiving Ig preparations (Jacobson *et al.*, 1993). This is not surprising considering all the uncertainty associated with attempting to identify the correlates of protective immunity and the ability of the virus to direct the immune response predominantly toward low affinity antibody responses (Kohler et al., 1992).

Absence of Working Embodiments

The disclosure fails to provide any working embodiments demonstrating the HIV-1 or -2 Vpr-specific antisera are effective at combatting HIV infection. Considering the unpredictability of the art and nature of the invention, the skilled artisan would clearly require suitable working examples before contemplating practicing the invention on an infected patient.

When all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation to practice the claimed invention.

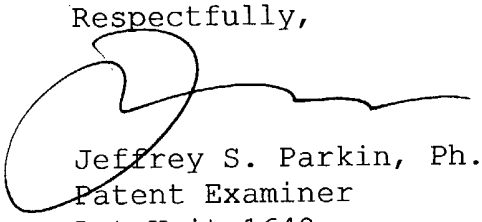
Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or

(571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600.

Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

24 June, 2004